

09/055,744



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/055,744	04/07/98	SIA	

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EXAMINER	
BUDENS, R	
ART UNIT	PAPER NUMBER
1648	9
DATE MAILED: 08/30/99	

This is a communication from the examiner in charge of your application.
 COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 6/8/99
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-15 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-15 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Examiner acknowledges Applicant's Amendment, Paper No. 5, filed June 8, 1999. In view of Applicant's Amendment, the status of the claims is as follows: Claims 1-15 are currently pending before the Examiner.

Applicant should note that neither the Amendment, Paper No. 5, filed June 8, 1999, nor the Information Disclosure Statement, Paper No 8, filed June 28, 1999 contained a proper PTO-1449. Therefore, the references have not been considered. Should Applicant desire that the references be made of record, Applicant should submit a proper PTO-1449.

The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. 602.1 and 602.02. The oath or declaration is defective because:

1) it does not properly reference the specification as originally filed. The declaration indicates that the specification "is attached hereto" when, in fact, the declaration was filed subsequent to the filing of the original specification;

2) the signature of inventor Michel Klein is absent in the wrong place and the date of signing of inventor Michel H. Klein is missing.

It is noted that Applicant has indicated that a new oath will be submitted (see Paper No. 5, page 3, third paragraph). No such new oath appears in the file record, however.

5 The rejection of claims 1-15 are rejected under 35 U.S.C. § 103 as being unpatentable over Blasevic et al., *AIDS Res. Hum. Retrovir.* 11(11):1335-1342, 1995 (Blasevic I, (U)) in view of Blasevic et al., *J. Acquired Immune Deficiency Syndromes* 6:881-890, 1993 (Blasevic II, (V)) and Schonbach et al., *Virology* 226:102-112, 1996 (W) is withdrawn in view of Applicant's arguments.

10 Claims 2-4 and 6-15 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record set forth in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. Claim 2 remains vague and indefinite in the recitation "HLA class II restricted T-helper epitopes" since it is unclear whether Applicant is actually referring to T cell stimulating epitopes of an HLA molecule or to HIV epitopes which are capable of interacting with an HLA molecule. Applicant has argued that the defines the T-helper molecule of claim 1. However, it remains unclear what epitopes are being referred to in the claim. Claims 6-7 and 12 are vague and indefinite in the recitation "corresponding to" or similar language since it is unclear what is intended to be encompassed by the language "corresponding to." Applicant argues that the terminology "corresponds to" defines an amino acid sequence. This is not persuasive. The terminology "corresponds to" does not set forth a specific sequence but only indicates some form of relationship to another sequence. Applicant should amend the claims to specifically claim a sequence.

30 Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record set forth

in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. Applicant argues that "Applicants have provided a sound immunization protocol for inducing a HIV-specific cytotoxic T-cell response in a host" (see Paper No. 5, page 4, last paragraph). However, Applicant has not provided any convincing objective evidence to support the assertion of enablement or to rebut the Examiner's objective evidence of non-enablement as evidenced by the teachings of Fahey et al., Fox, and Haynes as set forth in the last Office Action. As stated previously, Applicants have not provided any convincing evidence that their claimed invention is indeed useful as a therapeutic or preventative for HIV infection and have not provided sufficient guidance to allow one skilled in the art to practice the claimed invention with a reasonable expectation of success and without undue experimentation.

Further, as stated previously, Applicant's data is only directed to methods using MHC Class I HLA A2 molecules. Applicant has not set forth any evidence that the claimed methods could be used with MHC Class II molecules such as DR, DP and DQ molecules. Class I and Class II molecules differ in their structures and immunological specificities and it is unclear from the evidence of the specification that the two types of molecules can be used interchangeably in the claimed methods using the claimed peptides. Further, MHC restriction and regulation of the immune system may well limit the use of T helper molecules to a particular haplotype for a particular individual, analogous to tissue typing for transplantation antigens. In other words it is unclear that the claimed method utilizing a DR7 molecule would satisfactorily stimulate a CTL response in a DR4 individual. Stimulating specific T cell responses to a particular epitope is unpredictable. This unpredictability is magnified when one attempts to modify the epitope in any way such as suggested in claim 12. In the absence of sufficient teachings or working examples for stimulating HIV

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specific CTL responses, one skilled in the art would not be able to make and use the claimed peptides and methods with a reasonable expectation of success and without undue experimentation.

No claim is allowed.

5 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

10 **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE**
15 **ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.**

20 Papers relating to this application may be submitted to Group 1600 by facsimile transmission. The Fax number is (703) 308-4242. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also
5 be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Chris Eisenschenk, can be reached at (703) 308-0452.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at
10 (703) 308-0196.



Robert D. Budens
Primary Examiner
Art Unit 1648

15 rdb
August 29, 1999